MMed (Anaesthesiology) Research Report

The Prevalence of Skin Scars on Patients Previously Given Intramuscular Diclofenac Injections, Attending Universitas Academic Hospital Pain Clinic: A Descriptive Study

Dr D Tarloff
Department of Anaesthesiology, Faculty of Health Sciences, University of the Free State

INDEX

1. DECLARATION OF OWN WORK

I hereby declare that the research presented is my own work and that the data presented is true. I was guided by my study leader Prof G Lamacraft.

2. ACKNOWLEDGEMENTS

Professor G Lamacraft - Consultant at the Department of Anaesthesiology at the University of the Free State and Head of the Pain Control Unit
Professor G Joubert – Department of Biostatistics, University of the Free State
Staff of the Pain Control Unit, Universitas Academic Hospital, Bloemfontein

3. ABSTRACT

The Prevalence of Skin Scars on Patients Previously Given Intramuscular Diclofenac Injections, Attending Universitas Academic Hospital Pain Clinic: A Descriptive Study

INTRODUCTION

An incidental finding of scarring after intramuscular Diclofenac was made at the Pain Clinic, Universitas Academic Hospital, Bloemfontein. The primary objective of our study was to document the prevalence of scars caused by these injections and to determine how patients obtained intramuscular diclofenac and who administered it to them.

METHODS

A descriptive study was performed at the Pain Clinic. Informed consent was obtained and all patients attending (1st December 2013 – 31st August 2014) were included. Patients completed a questionnaire and the attending doctor examined the injection site. Data captured at examination included: site of injection(s) and skin changes.

RESULTS

131 patients were enrolled and data analysis was performed on 118 patients (these patients were completely sure injection they had received was diclofenac).

Scarring was identified in 8.5% of the study population. The majority of patients received the IM diclofenac from general practitioners (41.5%), private pharmacists (30.6%) and hospital pharmacies (15%). Only 17.5% of the patients always had a prescription and 78.8% had not been warned against skin scars.

Associated complications included pain, pruritus, erythema at the injection site, ulceration or skin damage, scarring and nausea. Four patients required medical treatment for a skin ulcer or abscess and 2 of these patients required surgical treatment.

DISCUSSION

This study shows that the prevalence of scarring after intramuscular diclofenac injections in our study population is 8.5%. In the population studied, 28.2% of patients had the drug administered by an unqualified person, and only 17.5% always had a prescription. This study shows that 78.8% of the study population had never been warned about skin scars as a potential side effect.

4. ABBREVIATIONS

IM – Intramuscular
NSAIDs – Non-steroidal anti-inflammatory drugs
BMI – Body mass index
Kg - Kilogram
Km - Kilometre
IV - Intravenous

5. RESEARCH PROTOCOL

Research Protocol

The Prevalence of Skin Scars on Patients Previously Given Intramuscular Diclofenac Injections, Attending Universitas Academic Hospital Pain Clinic: A Descriptive Study

Dr D Tarloff
Department of Anaesthesiology, Faculty of Health Sciences, University of the Free State

5.1. Title

The prevalence of skin scars on patients previously given intramuscular diclofenac injections, attending Universitas Academic Hospital Pain Clinic : A descriptive study

5.2. Researchers

The researchers that will be involved in the execution of the study are:

- Dr D Tarloff (debstarloff@yahoo.com; 051 4053307)
- Prof G Lamacraft (LamacraftG@ufs.ac.za; 051 4053613),

Prof G Lamacraft is currently a Consultant at the Department of Anaesthesiology at the University of the Free State and Head of the Pain Control Unit. Dr D Tarloff is a Registrar at the Department of Anaesthesiology at the above-mentioned university.

5.3. Introduction

Diclofenac is a non-steroidal anti-inflammatory drug. Non-steroidal anti-inflammatory drugs (NSAIDs) are a group of medications with analgesic, anti-inflammatory and antipyretic properties. They have been used as treatment for a wide spectrum of ailments including musculoskeletal or joint pain, soft tissue injury, acute gout, headaches and post-operative pain. The efficacy of NSAIDs is comparable, if not better, than narcotic analgesics without the side effects of respiratory depression, physical dependence, sedation or psychomotor effects. Due to this more favourable side effect profile, NSAID analgesics are very popular within accident and emergency departments of hospitals and offices of general practitioners. There are however adverse effects on the gastrointestinal tract, liver, kidney and the central nervous system. Bleeding tendencies and allergic reactions may result. There have also been sporadic reports of local reactions to NSAID injections.[1]

The Pain Clinic at Universitas Academic Hospital in Bloemfontein sees a variety of patients suffering with many different forms of chronic pain. Doctors working there have noted that some patients present with disfiguring skin scars that occurred after receiving intramuscular diclofenac (Voltaren®) injections elsewhere (it is not the practice of the Pain Unit to use or prescribe intramuscular diclofenac injections).

Intramuscular diclofenac injections is on the South African Essential Drug List for treatment of acute pain, although internationally its use is not so widespread due to the ugly scarring, potential ulceration and tissue loss that can result if administered incorrectly.[2]

In August 2003, the British Medical Journal published findings of a 25-year analysis of complications due to intramuscular diclofenac injections. A review of Novartis Global Safety Database of spontaneous and clinical trial reports for diclofenac ampoules from 1978 to 2003 revealed 115 reports of injection site necrosis, 37 reports of site abscess, 11 reports of injection site reaction, 6 reports of necrotizing fasciitis and 2 cases of necrotizing myositis." Pain on injection was only reported in 9 of the above-mentioned cases.[3]

This report must be balanced against how frequently diclofenac is used: Over a 25-year period it was estimated that an excess of 100 000 000 units of intramuscular diclofenac units were used for treatments and further analysis showed that the majority of individual reports were uncomplicated injection site necrosis.[3]

A particularly severe skin complication of intramuscular diclofenac is Nicolau Syndrome (embolia cutis medicamentosa). This is a rare occurrence following intramuscular injection of a variety of common drugs including NSAIDs, corticosteroids and penicillin. The clinical presentation is typically pain around the injection site, followed by erythema, liveoid patch, haemorrhagic patch and finally necrosis of the skin, subcutaneous fat and muscle tissue. There have been several case reports of Nicolau Syndrome following intramuscular diclofenac and these resulted in severe scarring and even death.[3,4,5]

Nicolau Syndrome was first described by Nicolau in 1925 following the use of bismuth salts for the treatment of syphilis. This phenomenon has now been related to the administration of a variety of drugs like corticosteroids, local anaesthetics and antihistamines.[4]

The pathogenesis of Nicolau Syndrome is not well understood but probably involves acute vasospasm, arteritis and thromboembolic occlusion of small arteries resulting in end organ damage. Diclofenac results in the vasocontrictive phenomenon as it inhibits prostaglandin synthesis due to cyclooxygenase inhibition, and thus can cause Nicolau Syndrome or milder forms of skin necrosis.[6]

The manufactures instructions for intramuscular diclofenac are very detailed and explicit, clearly stating that the injection should be administered by deep intra-gluteal injection (not in other sites such as the leg or arm), using strict aseptic techniques and not exceeding the recommended dose. Both subcutaneous and intravascular injection must be avoided to prevent skin scarring.[3,5]

In this study we wish to determine what the prevalence of such scarring is in our community, if any cases of ulceration or necrotizing fasciitis have occurred and if this prevalence is sufficiently significant that intramuscular diclofenac injections should be limited.

Some patients have also reported that they received diclofenac without prescriptions from pharmacists, particularly in rural areas. Furthermore, these patients have reported that the injections were given by persons other than appropriately trained health care professionals. Diclofenac is a schedule three drug which should be prescribed by a medical doctor and given by a trained health care professional. Medical professionals in this country should warn patients against this side-effect before administering intramuscular diclofenac injections.

5.4. Question/Aim

1. The first objective of this study is to document the prevalence of scars caused by intramuscular diclofenac injections in patients seen at the Pain Control Unit at Universitas Academic Hospital, in Bloemfontein, over a one-year period.

2. A second objective is to find out how patients obtained intramuscular diclofenac and who administered it to them.

5.5. Methodology

5.5.1. Study Design

The study will be a descriptive study.

5.5.2. Sample/Study Participants

All patients attending the Pain Clinic at Universitas Academic Hospital in Bloemfontein over a given one year period (1st November 2013 – 31st October 2014) will be included in the study. Approximately 1500 patients are seen in a year period and one-third to one-half might be expected to qualify for the study.

As patients may attend the Pain Clinic regularly in the one-year period, they will only be included once.

Informed consent will be obtained in writing from each patient who participates in the study.

5.5.3. Measurement

Each patient attending the Pain Clinic at Universitas Academic Hospital during the given time period will be asked if they have ever received an intramuscular diclofenac (Voltaren®) injection. If they answer "yes" they will be asked to participate in the study. The "Asking Nurse" will keep a record of how many people answer "yes" and "no".

Each patient participating in the study will be asked to read and sign the informed consent document, which will be stored in the patients' folder. This form will state why the study is being done and the role of the patient; i.e.: completion of the patient questionnaire and undergoing a non-invasive physical examination. The informed consent document and information document will be made available in English, Afrikaans and Sesotho. The staff in the Pain Clinic will assist the patients in completing the questionnaires.

Information will be collected confidentially. The patients' folder will be marked to assure each patient only participates once within the period of the study.

The questionnaire will be used to obtain basic demographic information such as age, gender, race, and co-morbid illnesses specifically diabetes mellitus. Patients, who did not receive the intramuscular injections from a doctor, will also be asked to indicate how far away they were living from a prescribing doctor at the time of the injection.

Following the demographic questioning, the questions regarding the diclofenac injections then ask who administered the intramuscular medications, how many times it was administered and was the aforementioned person appropriately trained i.e. a

medical doctor or nurse, or was it a family member with no medical training? They will be asked where they acquired the medication from e.g. a general practitioner or the pharmacist, and if they had a prescription at the pharmacy or not.

Questions about the injection will then follow. The patient will be asked the site of the injection, for example the buttock, thigh or upper arm? If there was a significant amount of pain during or following the injection? If there were any skin changes noticed around the injection site such as erythema (redness), indurations of the skin (in-drawing of the skin) or if an ulcer (open wound) formed a few days later, and how sure they are that it was a diclofenac injection responsible for the skin change that occurred?

They will also be asked if they now have residual skin changes such as hardening of the skin, scarring or a deformity caused by a healed ulcer.

Once the patient has completed the questionnaire, the area(s) of the aforementioned intramuscular diclofenac injection site(s) will be examined by the doctor (Anaesthetic Consultant or Registrar) working in the Pain Clinic.

The physical examination will be captured on a data form and will include the following information: the body mass index of the patient, the site of the intramuscular injection(s), if there are any skin changes such as scarring, ulcer formation or changes suggesting ulcer healing. If there are any colour changes or changes in sensation (increased or decreased sensation) associated with the scar.

If a lesion is observed, a photo will be taken as documentation, after a photographic consent form is completed by the patient.

The completed questionnaires and data forms will be kept by the secretary of the Pain Clinic and collected by Dr D Tarloff on a weekly basis.

5.5.4. Methodological and Measurement Errors

Recall bias may occur with completion of patient questionnaires, as they may not recall all the intramuscular diclofenac injections they may have had in the past.

Patients may have had injections with other medications and erroneously said they were diclofenac. Participants will be asked on the questionnaire to indicate how sure they are that they received a diclofenac injection and that it was this diclofenac injection that was responsible for the skin scar.

Incomplete questionnaires and data capturing sheets may result in inaccurate information. All the doctors working at the Pain Clinic will be given instruction as to capturing data correctly and completely, and making sure that the patients fully complete the patient questionnaire before they leave the clinic.

5.5.5. Pilot Study

A pilot study will be conducted on the first five patients selected for the study to determine the adequacy of the patient questionnaire, and how smoothly the evaluation

of the patient proceeds. If the methodology does not change after evaluation of the pilot study, these patients will be included into the actual study results.

5.6. Analysis

Analysis will be done by the Department of Biostatistics, University of the Free State. Results will be summarized by frequencies and percentages (categorical variables), means, and standard deviations of percentiles (numerical variables).

5.7. Implementation of Findings

On completion of the study, if the results show there are patients who have skin scars after intramuscular diclofenac injections, then these results will be presented to all departments at Universitas Academic Hospital involved in pain management of patients, and the importance of correct administration or alternative pain management strategies will be discussed at these meetings.
The results will also be used for my MMed Anaesthesiology qualification, as well as publication in a relevant journal.

5.8. Time Schedule

The study protocol will be submitted by the 23rd of September 2013 for review by the Ethics Committee of the Faculty of Health Sciences at the University of the Free State on the 17th of October 2013.

The study will be conducted from 1st November 2013 to 31st October 2014, pending approval by the Ethics Committee.

Data analysis and review of the study will be from the 1st November 2014 to 31st December 2014.
The findings of the study will be presented to all the relevant departments involved (as mentioned) and presented at the Faculty of Health Sciences Forum in 2015.

5.9. Budget

The cost of paper and photocopying consent forms and questionnaires' will be funded by the Pain Clinic at Universitas Academic Hospital.

Paper……R300
Photocopying……...R200
Total…….....R500

5.10. Ethical Aspects

The study protocol will be submitted to the Ethics Committee of the Faculty of Health Sciences for approval prior to initiation of the study.

All relevant hospital authorities will be informed of the study and permission asked for the study to be conducted in Universitas Academic Hospital. This will be done by a letter that can be found attached in the appendix section at the end of this protocol.

The patient information document and informed consent will be available in English, Afrikaans and Sesotho.

5.11. References

1. Chung CH. The use of injectable non-steroidal anti-inflammatory drugs in local accident & emergency practice. Hong Kong Journal of Emergency Medicine 2002; 9:65-71.
2. South African Essential Drug List 2010. Chapter 12:2-4
3. O'Sullivan DP, Collins J. Intramuscular diclofenac: 25 year worldwide safety perspective is vital to consider. 4 August 2003. URL: http://www.bmj.com/intramuscular-diclofenac-25-year-worldwide-safety-perspective-is-vital-to-consider.
4. Panariello L, Ayala F. Nicolau syndrome following intramuscular diclofenac injection: A case report. Dermatologic Therapy 2008; vol 21:10-12.
5. Lie C, Leung F, Chow SP. Nicolau syndrome following intramuscular diclofenac administration: a case report. Journal of Orthopaedic Surgery 2006; 4(1): 104-107.
6. Park H, Kim M, Park N, et al. Sonographic Findings in Nicolau Syndrome Following Intramuscular Diclofenac Injection: A Case Report. Journal of Clinical Ultrasound 2011; 39:111-113

6. RESEARCH ARTICLE

MMed (Anaesthesiology) Research Article

The Prevalence of Skin Scars on Patients Previously Given Intramuscular Diclofenac Injections, Attending Universitas Academic Hospital Pain Clinic: A Descriptive Study

Dr D Tarloff
Department of Anaesthesiology, Faculty of Health Sciences, University of the Free State

The Prevalence of Skin Scars on Patients Previously Given Intramuscular Diclofenac Injections, Attending Universitas Academic Hospital Pain Clinic: A Descriptive Study

D Tarloff. MBChB; DA(SA); FCA(SA); Registrar at the Department of Anaesthesiology, University of the Free State.

Prof G Lamacraft. MB,BS; MRCP; FRCA; Certificate in Pain Management (Australian and New Zealand College of Anaesthetists); Colleges of Medicine of South Africa Examination in Anaesthetics; Ph D Anaesthesiology (University of the Free State); Consultant at the Department of Anaesthesiology at the University of the Free State and Head of the Pain Control Unit.

6.1. INTRODUCTION

Intramuscular (IM) diclofenac (Voltaren®) is currently on the South African Standard Treatment Guidelines and Essential Medicines List for treatment of adults with acute pain.[1]

The current national contract for IM diclofenac in South Africa for the period 1 June 2014 to February 2017 is for 6 766 600 ampoules. The Free State province used 115 700 ampoules during the last 12 month period, and the usage at Universitas Academic Hospital in Bloemfontein (the Tertiary hospital in the Free State Province) was 1910 ampoules for the period 1st July 2014 to 31st June 2015.[2,3,4]

The widespread use of IM diclofenac in South Africa (as it is the only parenteral NSAID on the Essential Medicines List), is in contrast to its use in some countries, where its use has been limited due to the ulceration, scarring and tissue loss that can result with its administration.[5,6]

The Pain Clinic at Universitas Academic Hospital in Bloemfontein sees patients with many different forms of chronic pain, back pain being the most common presenting problem. Treating patients with low back pain often includes exposure of the patients' buttocks. Doctors in this clinic have frequently noted disfiguring skin scars on the buttocks of the patients that occurred after receiving intramuscular injections for their pain. These injections were given elsewhere and were often reported by the patients to be IM diclofenac (it is not the practice of this Pain Clinic to use or prescribe intramuscular diclofenac).

Some patients also reported that they had received IM diclofenac without prescriptions and that the injections were given by persons other than health care professionals.

The researchers therefore conducted this prospective questionnaire based study to determine the prevalence of skin scars due to IM diclofenac in their community. A second objective was to determine how patients obtained intramuscular diclofenac and who administered it to them.

6.2. METHODS

A prospective descriptive study was performed using a questionnaire and clinical examination.

The study protocol was approved by the Ethics Committee of the Faculty of Health Sciences of the University of the Free State.

All patients who attended the Pain Clinic at Universitas Academic Hospital in Bloemfontein over the nine-month period, 1st December 2013 to 31st August 2014, were included in the study. Patients who attended the Pain Unit more frequently over this study period were only included the first time they attended.

Informed consent was obtained from each patient. Consent documents and information forms were available in the three main languages of this region: English, Afrikaans and Sesotho.

Each patient who attended the Pain Clinic during the study period, was asked by the admitting Nurse if they had ever received an intramuscular pain relieving injection. If they answered “yes” they were asked to participate in the study. The Nurse kept a record of how many patients seen at the clinic were asked this question.

Patients included in the study completed a questionnaire and underwent a non-invasive physical examination of the injection site by the doctor (Anaesthetic Consultant or Registrar) working in the Pain Clinic.

Information was collected confidentially. The patient’s folder was marked to assure each patient only participated once within the period of the study.

The questionnaire asked questions regarding the patient’s demographics, if they had diabetes mellitus, the name of the intramuscular pain relieving injection, who administered the IM injection, at which site it was administered, if they had a skin scar or other complications at the injection site, whether or not they had been warned about a risk of skin scars and if they had a prescription for the IM injection when they obtained it from a pharmacy. They were also asked how recently the IM injection associated with the scar occurred and what type of treatment (medical or surgical) was needed.

The admitting nurse recorded the patient’s weight and height on the data collection form. The BMI was then calculated from these.

During the physical examination of the patient, the following information was recorded: the site of the intramuscular injection(s), skin changes at the injection sites e.g. scarring, ulcer formation or changes suggestive of a healed ulcer. Where there was a scar, its size was measured and it was noted if there were any colour changes or changes in sensation (increased or decreased sensation) associated with the scar.

If a scar was observed, a photograph was taken as documentation, after consent for the photo was obtained from the participant.

A pilot study was conducted on five patients in the month prior to study period. This resulted in some questions being rephrased. These changes were approved by the Ethics Committee before commencement of the study. The results from the pilot study were not included in subsequent data analysis.

6.3. STATISTICAL ANALYSIS

Data analysis was performed by the Department of Biostatistics of the University of the Free State. Results were summarized by frequencies, percentages (categorical variables), means and standard deviations of percentiles (numerical variables).

6.4. RESULTS

Two hundred and nineteen patients were recorded as having attended during the study period and being asked if they had ever received a pain relieving injection. Of these, 131 answered “yes” and were then asked to participate in the study.

The mean age of the participating patients was 54.2 years (SD 12.1 years; range 23-80 years).

The body mass index (BMI) was recorded in 127 patients. The median was 29.2kg/m^2 (range 16.2-56.6kg/m^2)

Almost two-thirds (66.4%) of the patients were female.

Seventeen (13%) patients had Diabetes Mellitus.

The median number of pain relieving injections received by each patient was 8 (range 1-95).

One hundred and twenty-five patients (95.4%) responded that the pain relieving injection they had received was IM diclofenac or “Voltaren”. The remaining 6 participants were unsure of the name of the pain relieving injection.

Of the 125 patients that responded the injection was IM diclofenac, 94.4% (n=118) were 100% sure that it was IM diclofenac, 4% (n=5) were 60-90% sure that the injection was IM diclofenac, and 1.6% (n=2) were less than 60% sure of the name of the injection.

The data analysis was then only continued for the 118 patients who indicated they were 100% sure the pain relieving injection they had received was IM diclofenac. Ten of these patients were identified as having a scar by the examining doctor, and 50% of these patients with scars had a BMI >30kg/m^2. Three patients with scars had diabetes (2.5% of the 118 final patients) but the association was not statistically significant (p=0.38).

Their response to the question on “Who administered the pain relieving injection?”, was that in most cases, it had been given by a general practitioner (45%, n=66). Other people who had given the injections included: a trained nurse (26%, n=39), a pharmacist (20%, n=29), a family member with medical training (4%, n=6), a family member without medical training (2%, n=3), a spouse (medical training was not specified) (0.5%, n=1) and self-administered (2.5%, n=4), (Figure 1). (Some patients gave more than one answer in this question, n=148.)

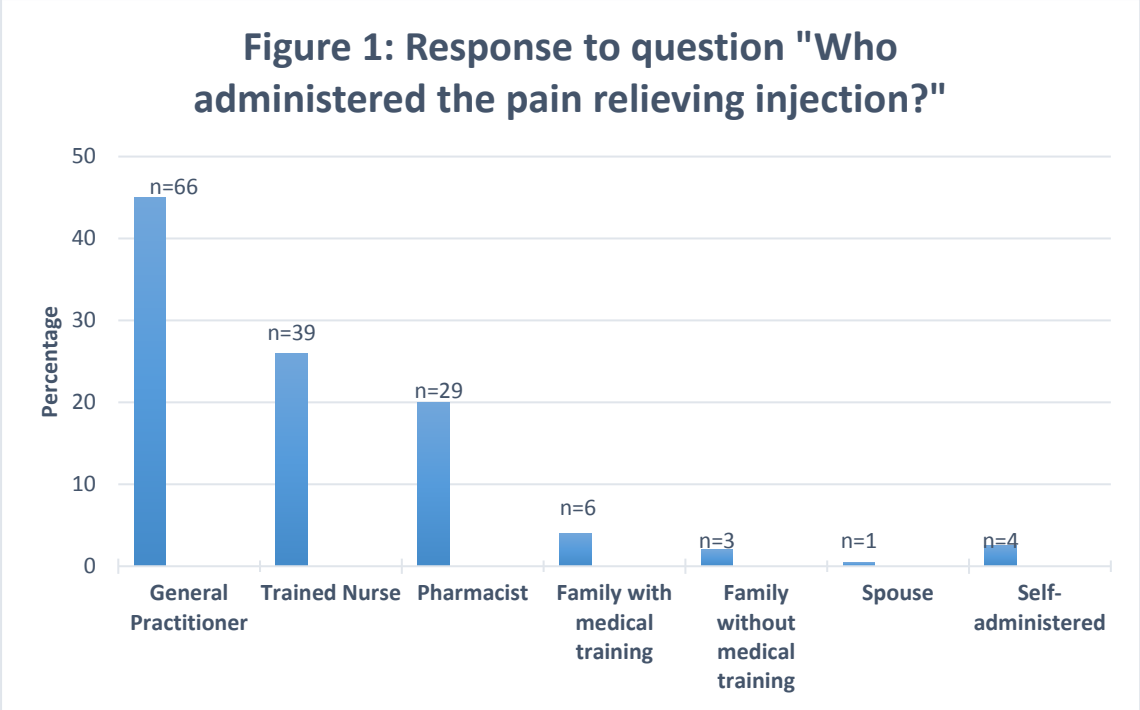

Figure 1: Response to the question on who administered the pain relieving injection. (n=148)

When asked "Where did you obtain the injection?" 61 (41.5%) answered a general practitioner, 45 (30.6%) a private pharmacist, 22 (15%) a hospital pharmacy and 19 (12.9%) answered "other" (7 at home, 2 from nurses at the pharmacy or hospital, 2 from a clinic, 5 in hospital and 1 participant did not specify). (Figure 2) (Some patients gave more than one answer in this question, n=147.)

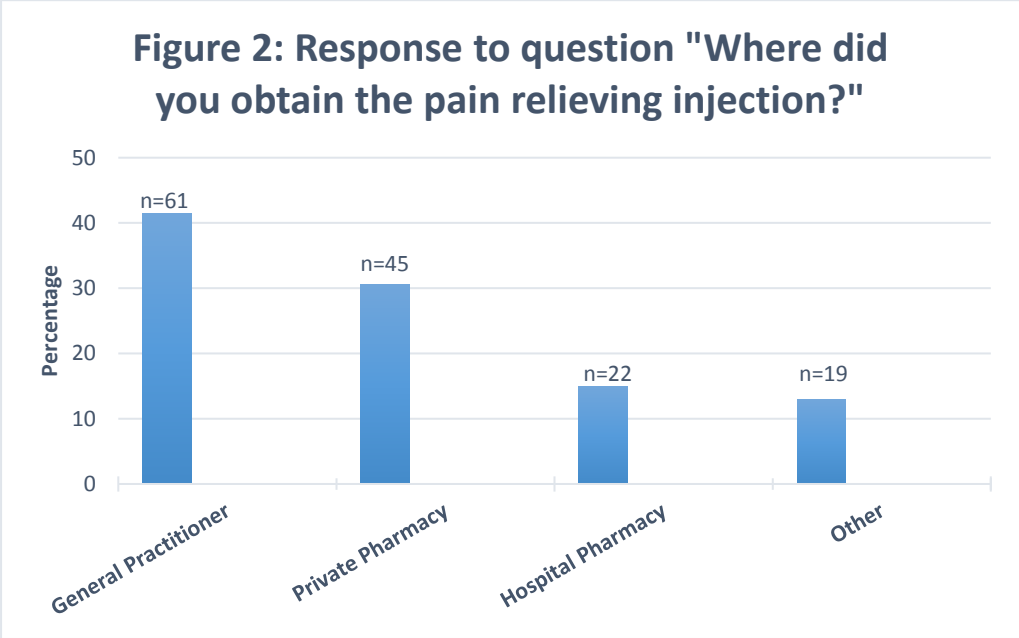

Figure 2: Response to the question on where they obtained the pain relieving injection (n=147)

Fifty-seven (48.3%) patients had obtained the IM diclofenac from either a hospital or private pharmacy.

To the question: "If you received the injection from a pharmacist, did you have a prescription?", most patients (66.7%) answered that they never had a prescription for diclofenac (Table 1).

"If you received the injection from a pharmacist, did you have a prescription?"	**Percentage of patients (n=57)**
Never	66.7% (38)
Sometimes	15.8% (9)
Always	17.5% (10)

Table 1: Response to question on whether patient had a prescription for diclofenac.

Regarding the 38 (66.7%) patients who received IM diclofenac without a prescription, they lived a median of 3 kilometers from a medical doctor (range: 1- 32 kilometers).

To the question: "Have you ever been warned that you may get a skin scar from IM diclofenac injection?", 93 (78.8%) patients indicated they had not been warned.

Most patients received the injections recently: 80 (67.8%) patients had received an IM diclofenac injection in the last year, 22 (18.6%) had received it in the last five years and 16 (13.6%) had received it more than five years ago.

Regarding the ten patients who had a scar from the IM diclofenac, the injection associated with the scar occurred within the last year in 70% of patients, within the last 5 years in 10% of patients and in 20% the associated injection was more than five years ago.

The most common complications noted by the patients after the IM diclofenac were pain, pruritus or erythema at the injection site. Other complications included ulceration or skin damage, scarring and nausea. Sixty-five (46.4%) of the 118 patients who answered the question had no skin changes at the site of the injection *(Table 2).* (Some patients gave more than one answer in this question, n=140.)

Complications noted by the patients after the diclofenac injection	**n=140 (%)**
Pain at injection site	27 (19.3%)
Pruritus at injection site	23 (16.4%)
Erythema at injection site	19 (13.6%)
Ulceration/ skin damage at injection site	3 (2.1%)
Scarring at injection site	2 (1.4%)
Nausea	1 (0.8%)
Nil skin changes	65 (46.4%)

Table 2: Complications noted after the pain relieving injections

Most of the injections received were into the buttocks. Other sites included the patients' arm, thigh, shoulder, directly into the painful muscle, the stomach, the knee and back *(Table3).* (Some patients gave more than one answer in this question, n=128.)

Site of administered injection	**n=128 (%)**
Buttock	110 (85.8%)
Arm	6 (4.7%)
Thigh	6 (4.7%)
Shoulder	2 (1.6%)
Painful muscle	1 (0.8%)
Stomach	1 (0.8%)
Knee	1 (0.8%)
Back	1 (0.8%)

Table 3: Site of injection

Regarding the ten patients with scars, 4 (3.4%) patients required medical treatment for a skin ulcer or abscess: 1 received an antibiotic, 1 used betadine ointment and 1 patient used an unspecified ointment. Two of these patients, one of whom needed medical treatment, also required surgical treatment in the form of incision and drainage of the abscess.

Of the 10 patients who had scars, 2 scars were on the upper arm in the deltoid region and 10 scars were on the buttocks. No scars were recorded on the upper thigh. Two of the patients had a scar on the deltoid area as well as the buttocks.

Three patients experienced ongoing hyperalgesia or allodynia over the site of the scar, and 2 patients had decreased sensation at the site of the scar.

The size of the scars ranged from 5x5mm^2 to 30x40mm^2.

Skin colour changes over the scar were observed in 4 patients and were described as either a blue discolouration or hyperpigmentation.

Participant with a scar	**BMI (kg/m$^{2)}$**	**Diabetes Mellitus**	**Site of the scar(s)**	**Injection site complications reported by patient**	**Treatment needed**
1	26.9	-	Buttock	Erythema Nodule	Antibiotics Incision & Drainage
2	25.7	-	Buttock and Deltoid	Pain, Scarring,	-

				Pruritus, Ulcer, Blue discolouration	
3	29.8	-	Buttock	Pain, Pruritus	-
4	25.0	-	Buttock	Pain, Pruritus	-
5	33.8	+	Buttock	Pruritus	-
6	29.4	-	Buttock	Pruritus, Ulcer	Unspecified ointment
7	37.2	+	Buttock	Blue discolouration	-
8	34.3	-	Buttock/Deltoid	Pain Hyper-pigmentation	Incision & Drainage
9	37.6	-	Buttock	Pain, Erythema, Pruritus	-
10	32.3	+	Buttock	Blue discolouration	Betadine ointment

Table 4: Summary of the 10 patients with scars

6.5. DISCUSSION

Diclofenac is a non-steroidal anti-inflammatory drug (NSAID) with analgesic, anti-inflammatory and antipyretic properties. NSAIDs are used to treat a wide spectrum of ailments including musculoskeletal or joint pain, soft tissue injury, acute gout, renal colic and post-operative pain. The parenteral route of administration is often favoured for acutely painful conditions, with the IM route often used. When given intravenously, diclofenac has to be given as a slow infusion and is associated with thrombophlebitis.[7]

Skin complications from IM diclofenac have previously been reported. In August 2003, the British Medical Journal published findings of a 25-year analysis of complications due to intramuscular diclofenac injections. A review of Novartis Global Safety Database of spontaneous and clinical trial reports for diclofenac ampoules from 1978 to 2003 revealed 115 reports of injection site necrosis, 37 reports of site abscess, 11 reports of injection site reaction, 6 reports of necrotizing fasciitis and 2 cases of necrotizing myositis. Pain on injection was only reported in 9 of these cases. The Novartis review also compared these complications with the frequency that IM diclofenac was used. Over the 25-year period it was estimated that an excess of 100 000 000 units of intramuscular diclofenac units were used for treatments (4 000 000 per annum) in the United Kingdom, giving an incidence of lesions of 2.25×10^{-6}. The review also noted a study by Serratrice of 10 167 cases of IM diclofenac that gave an incidence of abscess of 0.05%, necrosis at the site of 0.02% and pain at the injection site of 5.6%.[8]

The results of our study gives a much higher risk of scars from IM diclofenac injections than previously described, with an 8.5% prevalence of scarring after IM diclofenac. The markedly different results from the Novartis Database implies that there may be considerable underreporting of skin lesions resulting from IM diclofenac injections.

Whilst skin scars can be unsightly or painful (30% of the scars in this study were associated with hyperalgesia or allodynia), more severe complications have resulted from the skin complications of IM diclofenac, evidenced in our study by two patients requiring incision and drainage of injection site abscesses.

A particularly severe skin complication of intramuscular diclofenac is Nicolau Syndrome (embolia cutis medicamentosa). This is a rare occurrence, that was first described by Nicolau in 1925, following the use of bismuth salts for the treatment of syphilis. This phenomenon has now been related to the administration of a variety of drugs such as intramuscular injections of diclofenac as well as other commonly medicines including corticosteroids, antihistamines, local anaesthetics and penicillin. The clinical presentation is typically pain around the injection site, followed by erythema, liveoid patch, haemorrhagic patch and finally necrosis of the skin, subcutaneous fat and muscle tissue. There have been several case reports of Nicolau Syndrome following intramuscular diclofenac and these resulted in severe scarring and even death.[8,9,10]

The pathogenesis of Nicolau Syndrome is not well understood but probably involves acute vasospasm, arteritis and thromboembolic occlusion of small arteries resulting in end organ damage. Diclofenac results in the vasocontrictive phenomenon as it inhibits prostaglandin synthesis due to cyclooxygenase inhibition, and thus can cause Nicolau Syndrome or milder forms of skin necrosis.[11]

The manufacture's instructions for the administration of IM diclofenac are detailed and explicit, clearly stating that the injection should be administered by deep intra-gluteal injection (not in other sites such as the leg or arm), using strict aseptic techniques and not exceeding the recommended dose. It also states that both subcutaneous and intravascular injection must be avoided to prevent skin scarring.[8,10]

In South Africa, IM diclofenac is a Schedule 3 drug which should only be dispensed with a prescription by a medical doctor and administered by a trained health care professional. A Pharmacist may administer IM diclofenac provided they have received the necessary training and are competent in the technique.[12]

The results of this study show that IM diclofenac is being inappropriately dispensed by some pharmacists; two-thirds of the patients who were dispensed IM diclofenac from the pharmacy received this drug without a prescription. This is a worrying result and implies there are pharmacists who are dispensing this drug illegally. This cannot be excused by claiming that these participants were not able to visit a doctor to obtain a prescription for the injection owing to them living in remote or rural areas, as most patients lived only a few kilometers away from a medical doctor and none more than 32km.

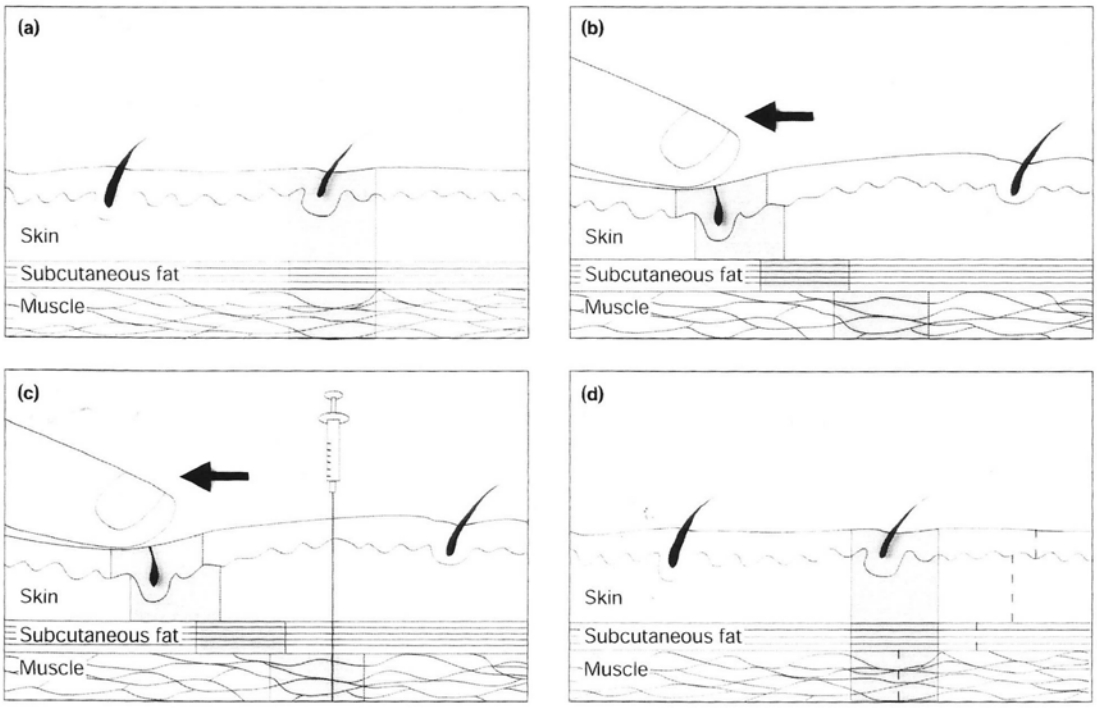

Figure 3: The Z-track method of intramuscular injection can minimize subcutaneous irritation by blocking the needle track after injection and should be adopted as a standard procedure. (a) Step 1: the skin, subcutaneous fat, and muscle lie in normal position. (b) Step 2: pull the skin and subcutaneous layer 1 cm down to de-align with underlying muscle. (c) Step 3: insert the needle at 90 degrees, inject and withdraw. (d) Step 4: release the finger to break the needle track, trapping the drug inside the muscle (broken lines indicate the original needle track).[10]

Another concerning finding was that several patients received IM diclofenac injections from unauthorized people or even gave it to themselves (it is assumed that the 20% of participants in this study who received the injection from a pharmacist, received it from one trained in this technique). This suggests that when IM diclofenac is dispensed, there should be tighter regulations to ensure that the patient only receives the injection from an appropriately trained health care professional. Incorrect administration was evidenced by the observation that two of the scars from IM diclofenac were on the upper arms of the participants.

Before receiving IM diclofenac, patients should be warned of the potential for skin scarring. This is clearly stated in the package insert. The scars are probably more common than previously thought, as 8.5% of patients in this study who received IM diclofenac had scars from this injection. Despite this, 78.8% of the study population had never been warned against skin scars as a potential side effect. Medical professionals should warn patients against this side effect when prescribing IM diclofenac, as this has legal implications if a scar results.

One cannot argue that as the scars are on the buttocks and not usually visible for many people, that it is not potentially a concern for them. There are some people who do not wish to have scars on their buttocks for their own personal reasons and cognizance should be made of this before prescribing IM diclofenac to patients. Furthermore, some of the scars were large and some were chronically painful, demonstrating that there is a significant morbidity attached to these scars.

Diabetics are more at risk of developing infections after any invasive procedure. If an IM diclofenac injection site became infected the risk of scars would increase. There is a suggestion from this study that diabetes mellitus may be a risk factor for developing scars from IM diclofenac, as the prevalence of skin scars in diabetic participants was double that in non-diabetics, but this was not statistically significant. A larger study is necessary to determine if diabetes is a risk factor.

A major limitation of this study is that it relied on the memory of the patients completing the questionnaire. Recall bias may have occurred to exaggerate symptoms. They may not have accurately recalled all the intramuscular diclofenac injections they may have had in the past, and other facts might have been forgotten. Patients may have had injections with other medications and erroneously said it was diclofenac (although it was asked if they were 100% sure of the IM injection they had received). Some patients did not answer all the questions and data was lost in this small number of cases. Another limitation to this study is that some patients who attended the Pain Clinic during the study period were not asked to be in the study in the first place, and skin scars may have been missed.

A larger prospective study to investigate the risk of skin scars from IM diclofenac injections is required. Until this has been done, patients should be warned they may develop a skin scar after IM diclofenac (as stated in the package insert). This warning should be documented as having been given, and the oral route used where possible.

6.6. CONCLUSION

The prevalence of skin scarring after IM diclofenac injections is probably higher than previously reported, and was found to be 8.5% in this study. A large percentage of these patients had never been warned about the risk of such scarring.

Patients are aquiring IM diclofenac without prescriptions and not always being injected by appropriately trained persons. This is an issue of concern and requires further investigation by the Pharmacy Council.

6.7. REFERENCES

1 Hospital Level Adults. Standard Treatment Guidelines and Essential Medicines List 2012. Essential Drugs Programme South Africa. Department of Health.

2 HP06-2014 SVP: Supply and delivery of small volume parenteral and insulin devices to the Department of Health for the period 1 June 2014 to 28 February 2017.

3 Personal Communication with the Assistant Manager of Pharmaceutical Services – Medpharm, Free State Department of Health. Information from Medsas System. 9 November 2015

4 Personal Communication: Ms Z Loots. Pharmacist at Universitas Academic Hospital. 9 July 2015

5 19th WHO Model List of Essential Medicines (April 2015)

6 O'Sullivan DP, Collins J. Managing acute renal colic across the primary-secondary care interface: a pathway of care based on evidence and consensus. Last viewed 2014/12/08; URL: http://www.bmj.com/rapid-response/2011/10/29/intramuscular-diclofenac-25-year-worldwide-safety-perspective-is-vital-to-consider.

7 Chung CH. The use of injectable non-steroidal anti-inflammatory drugs in local accident & emergency practice. Hong Kong Journal of Emergency Medicine 2002; 9:65-71.

8 O'Sullivan DP, Collins J. Intramuscular diclofenac: 25 year worldwide safety perspective is vital to consider. 4 August 2003. URL: http://www.bmj.com/intramuscular-diclofenac-25-year-worldwide-safety-perspective-is-vital-to-consider.

9 Panariello L, Ayala F. Nicolau syndrome following intramuscular diclofenac injection: A case report. Dermatologic Therapy 2008; vol 21:10-12.

10 Lie C, Leung F, Chow SP. Nicolau syndrome following intramuscular diclofenac administration: a case report. Journal of Orthopaedic Surgery 2006; 4(1): 104-107.

11 Park H, Kim M, Park N, et al. Sonographic Findings in Nicolau Syndrome Following Intramuscular Diclofenac Injection: A Case Report. Journal of Clinical Ultrasound 2011; 39:111-113

12 Personal Communication: Ms K Malaku. Manager: Professional Affairs. The South African Pharmacy Council 18th November 2015.

7. APPENDIX

7.1 Letters to the clinical head of Universitas Academic Hospital and Head of Anaesthesiology Department, University of the Free State

7.2 Information documents for participants in the study (English, Afrikaans and Sesotho)

7.3 Consent Documents
- 7.3.1 Consent to participate in the study
- 7.3.2 Photographic consent

7.4 Data Capturing Form

7.5 Data Form for Medical Doctor

7.6 Permission Documents

7.7 Ethics Committee Approval

7.1. LETTERS TO HOSPITAL

Department of Anaesthesiology
Faculty of Health Sciences
University of the Free State
Bloemfontein
9321

Tel 051 4053071
Cell 083 383 0093
Fax 051 4443414
Email: debstarloff@yahoo.com

Dr N van Zyl
Universitas Hospital
1 Logeman Street
Bloemfontein
9321

Dear Dr N van Zyl

The Prevalence of Skin Scars on Patients Previously Given Intramuscular Diclofenac (Voltaren®) Injections, Attending Universitas Academic Hospital Pain Clinic : A Descriptive Study

Patients will be asked to complete a questionnaire and undergo a non-invasive physical examination, where they had previously had a diclofenac injection, as part of the study to determine if they have a skin scar as a result of a previous intramuscular diclofenac injection. They will also be asked if a health care professional administered the diclofenac and if they had a prescription for the drug.

Informed consent will be obtained prior to evaluation of each study candidate.

With your permission I would like to initiate the study on the 1st of November 2013, pending Ethics Committee approval (17th October 2013)

If you have any further queries regarding any aspect of the study please do not hesitate to contact me.

Sincerely yours,

_____

Dr D Tarloff

Registrar

Department of Anesthesiology

University of the Free State

7.2. INFORMATION DOCUMENTS

The Prevalence of Skin Scars on Patients Previously Given Intramuscular Diclofenac Injections, Attending Universitas Academic Hospital Pain Clinic : A Descriptive Study

Dear Participant

I, Dr D Tarloff, am doing a research project on the prevalence of skin scars as a result from diclofenac (Voltaren®) injections. Research is the process by which we learn the answers to our questions. In this study we wish to learn how many patients attending the Pain Clinic have skin scars after previous diclofenac (Voltaren®) injections.

We are asking/inviting you to participate in this research study.

It is a descriptive type of study in which we wish to determine how many of our patients attending the Pain Clinic have had scarring, ulceration or any form of permanent skin damage after diclofenac (Voltaren®) injections.

We also want to gather information about who is giving patients these injections and if patients have a prescription for this drug when they obtain it.

There will be no remuneration or cost for participants taking part in this study.

Participation is voluntary, and refusal to participate will involve no penalty or loss of your benefits. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. There are no risks for participating in this study.

The results of the study may be published. Participants may contact the researcher for information regarding regarding study findings,

Confidentiality: Collection of all information and data capturing will be done confidentially.

Contact details of researcher(s) – Dr D Tarloff 051 4053307; Prof G Lamacraft 051 4053613.

Contact details of Secretariat and Chair: Ethics Committee of the Faculty of Health Sciences, University of the Free State – for reporting of complaints/problems: Telephone number (051) 4052812

7.3. CONSENT DOCUMENT

CONSENT TO PARTICIPATE IN RESEARCH

The Prevalence of Skin Scars on Patients Previously Given Intramuscular Diclofenac Injections, Attending Universitas Academic Hospital Pain Clinic: A Descriptive Study

You have been asked to participate in a research study.

You have been informed about this study by the doctor working in the Pain Clinic at Universitas Academic Hospital.

You may contact Dr D Tarloff at 051 4053307 at any time if you have questions about the research.

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to terminate participation.

If you agree to participate, you will be given a signed copy of this document as well as the participant information sheet, which is a written summary of the research.

The research study, including the above information has been verbally described to me. I understand what my involvement in the study means and I voluntarily agree to participate.

_____ _____

Signature of Participant Date

_____ _____

Signature of Witness Date
(Where applicable)

_____ _____

Signature of Translator Date

_____

Dr D Tarloff

CONSENT DOCUMENT

PHOTOGRAPHIC CONSENT

The Prevalence of Skin Scars on Patients Previously Given Intramuscular Diclofenac Injections, Attending Universitas Academic Hospital Pain Clinic: A Descriptive Study

I, _____, hereby give consent for a photo to be taken, and published in a medical journal, of the identified skin lesion I have after receiving a diclofenac (Voltaren®) injection.

I understand that this photograph will not identify me in any manner, and that I will receive no remuneration for the photograph.

_____ _____
Signature of Participant Date

_____ _____
Signature of Witness Date
(Where applicable)

_____ _____
Signature of Translator Date
(Where applicable)

_____
Dr D Tarloff

INLIGTINGSTUK

Die Voorkoms van Vel Letsels in Pasiente Voorheen met Binnespierse Diclofenac Inspuitings Behandel te Universitas Akademie Hospital Pyn Kliniek: ‘n Beskrywende Studie.

Geagte Deelnemer

Ek, Dr D Tarloff, doen navorsing oor die voorkoms van vel letsels as gevolg van diclofenac (Volaren®) inspuitings. Navorsing is die manier waarop ons antwoorde kry vir ons vrae. In hierdie navorsing wil ons leer hoeveel van die pasiente wat die pyn kliniek bywoon vel letsels het as gevolg van diclofenac (Voltaren®) inspuitings.

Ons vra/nooi u om deel te wees van hierdie navorsing.

Dit is ‘n beskrywende tipe navorsing om ons in staat te stel om te bevestig hoeveel van ons pasiente wat die pyn kliniek bywoon enige letsels, sere of enige soort permanente skade as gevolg van Voltaren® inspuitings het.

Graag wil ons inligting bymekaar maak oor wie die inspuitings toedien, en of die pasiente ‘n voorskrif vir hierdie middel het wanneer hulle dit ontvang het.

Daar sal geen geldelike vergoeding vir deelnemers in hierdie studie wees nie. Deelname is vrywillig en weiering om deel te neem sal geen nadeel of staking van voordele inhou nie. U mag u deelname enige tyd staak sonder enige nadeel of staking van voordele wat u toekom nie. Daar is geen risikos aan u deelname in hierdie navorsing nie.

Die resultate van die studie mag gepubliseer word. Deelnemers mag die navorser kontak met betrekking tot inligting van studie resultate.

Vertroulikheid: Versameling van alle inligting en data verwerking sal vertroulik gedoen word.

Kontak besonderhede van navorser(s): Dr D Tarloff 051 4053307; Prof G Lammacraft 051 4053613

Kontak besonderhede van Sekretariaat en Voorsitter: Etiese komitee van die Fakulteit Gesondheidswetenskappe, Universiteit Vrystaat – vir rapporteer van klagtes/probleme: 051 4052812

TOESTEMMING DOKUMENT

TOESTEMMING OM IN NAVORSING DEEL TE NEEM

Die Voorkoms van Vel Letsels in Pasiente Voorheen met Binnespierse Diclofenac Inspuitings Behandel te Universitas Akademie Hospital Pyn Kliniek: ‘n Beskrywende Studie.

U is versoek om deel te wees van hierdie navorsing.

U is ingelig van hierdie navorsing deur die dokter werksaam by die Pyn Kliniek te Universitas Akademie Hospitaal.

U kan Dr D Tarloff by 0514053307 kontak oor enige vrae wat u in verband met die navorsing mag hê.

U deelname in hierdie navorsing is vrywillig en u sal nie gepenaliseer word of enige voordele verloor indien u weier om deel te neem of u deelname sou beëindig.

Indien u deelneem, sal u ‘n getekende afskrif van hierdie dokument, sowel as die toestemming dokument, wat ‘n opsomming van die navorsing behels, ontvang.

Die navorsing en die inligting soos bo is mondelings aan my verduidelik. Ek verstaan dat my deelname in die navorsing beteken dat ek vrywillig instem om deel te neem en gaan geen vergoeding ontvang.

_____ _____

Handtekening van deelnemer Datum

_____ _____

Handtekening van getuie Datum

_____ _____

Handtekening van tolk (waar toepaslik) Datum

_____

Dr D Tarloff

TOESTEMMING DOKUMENT

FOTOGRAFIESE TOESTEMMING

Die Voorkoms van Vel Letsels in Pasiente Voorheen met Binnespierse Diclofenac Inspuitings Behandel te Universitas Akademie Hospital Pyn Kliniek: ‘n Beskrywende Studie.

Ek, _____, gee hiermee toestemming om ‘n foto te laat neem en publiseer in ‘n mediese joernaal, van die vel letsel soos geidentifiseer nadat ek ‘n diclofenac (Voltaren®) inspuiting ontvang het.

Ek verstaan dat die foto my nie identifiseerbaar sal laat nie, en dat daar geen geldelike vergoeding vir deelname sal wees nie.

_____ _____

Handtekening van deelnemer Datum

_____ _____

Handtekening van getuie Datum

_____ _____

Handtekening van tolk (waar toepaslik) Datum

_____

Dr D Tarloff

TOKOMANE YA TSEBISO

Kgonahalo ya mabadi letlalong la mokudi ya filweng ente ya Diclofenac kliniking ya taolo ya bohloko (pain)sepetleleng sa Universitas Academic.

Monkakarolo ya ratehang

Nna, Ngaka D Tarloff, ke etsa patlisiso ya thuto ka kgonahalo ya mabadi letlalong ka mora tshebediso ya ente diclofenac (Voltaren®). Ho thuto patlisiso ena ke tsela eo re ithutang ho araba dipotso tseo re di botswang. Thutong ena re lakatsa ho ithuta hore ke bakudi ba ba kae ba tsamayang kliniking ya taolo ya bohloko (pain) ba fumanang mabadi ka mora ho fumana ente ya diclofenac (Voltaren®).

Re o kopa/mema ho nka karolo thuto patlisisong ena.

Ke thuto e hlalosang, eo ka yona re lekang ho fumana hore ke bakudi ba bakae ba tsamayang kliniki ya taolo ya bohloko (pain) ba fumang mabadi, maqeba kapa seso sa mofuta ofe kapa ofe ka ente ena.

Re lakatsa ho bokanya tsebo ka hore ke mang ya fang bakudi ente ena, hape bakudi ba na le lengolo la ngaka la moriana ona ha o o fumana.

Ha ho morokotso kapa patala thutong ena. Ho nka karolo ke boithaopi, ho hanetsa ho nka karolo ha ho patadiswe kapa ho lahlehelwa ke ditokelo tsa mokudi. O ka ikhula nako efe kapa efe. Ntle ho kotlo kapa tahlehelo ya ditokelo jwalo ka mokudi. Ha ho kotsi ho nka karolo thutong ena.

Sepheto sa teko se ka phatlalatswa. Bankakarolo ba ka botsa mong wa diphuphutso mabapi le hlahiso leseding la sepheto sa teko.

Sephiri: Tsohle tse bokeleditsweng thutong ena di tla nkuwa e le sephiri.

Dinomoro tsa mohala tsa ngaka e etsang dipatlisiso: ke Ngaka D Tarloff 051 4053307; Prof G Lammacraft 051 4053613

Ka botlalo letsetsa mongwaledi yeo ikamahanyang le tsa thuto ya botho le mahlale, Unibesithing ya Foreistata: Bakeng sa boipelaetso/mathata, letsetsa nomoro ye ya mohala 051 4052812

TOKOMANE YA TUMELLANO

TUMELLANO YA HO NKA KAROLO DIPATLISISONG

Kgonahalo ya mabadi letlalong la mokudi ya filweng ente ya Diclofenac kliniking ya taolo ya bohloko (pain) sepetleleng sa Universitas Academic.

O kupilwe ho nka karolo patlisisong ya thuto ena.

O tsebitswe ka ho phethehala mabapi le thuto ena e ngaka a tlilong ho e etsa kliniking ya taolo ya bohloko.

O ka ikopanya le ngaka D Tarloff nomorong ena ya mohala ke 051 405 3307 nako enngwe le e nngwe mabapi le dipotso ka patlisiso ena.

O nka karolo ka boithaopo, okeke wa ahlolwa kapa wa lahlehelwa ke ditokelo, ha o hana ho nka karolo kapa o nka qeto ya ho ikgula patlisisong ena.

Ha o dumela ho nka karolo, o tla fumana tokomane e tekenilweng le tokomane ya ho nka karolo e leng kgutsufatso ya patlisiso.

Tsohle tse hlahang patlisisong ena ke di bolelletswe, ke utlwisisa hore ho nka karolo ha ka ho bolelang, hape ke dumela ka ho ithaopo.

_____	_____
Monkakarolo - saena	Letsatsi
_____	_____
Paki – Saena	Letsatsi

_____
Dr D Tarloff

TOKOMANE YA TUMELLANO

TUMELLANO YA HO NKWA SENEPE

Kgonahalo ya mabadi letlalong la mokudi ya filweng ente ya Diclofenac kliniking ya taolo ya bohloko (pain) sepetleleng sa Universitas Academic.

Nna, _____, ke fana ka tumellano ya hore senepe sa ka se kenngwe bukaneng ya tsa bongaka ho bontsha mabadi letlalong ka mora ho fumana ente ya diclofenac (Voltaren®).

Ke utlwisisa hore senepe sena ha se na hlahisa boitsebiso ba ka ka tsela efe kapa efe, ebile hape ha ke na fumana morokotso.

_____ _____

Monkakarolo - saena Letsatsi

_____ _____

Paki – Saena Letsatsi

_____

Dr D Tarloff

7.4. DATA CAPTURING FORMS

PATIENT QUESTIONNAIRE
The Prevalence of Skin Scars on Patients Previously Given Intramuscular Diclofenac Injections, Attending Universitas Academic Hospital Pain Clinic : A Descriptive Study

Today's Date_____ 1-6 | | | | | | |

Patient Number_____ 7-9 | | | |

Please mark the appropriate box (or boxes if more than one correct answer) with an X.

1. Age 10-12 | | | |

_____

2. Gender 13 |

1
2

1) Male
2) Female

3. Race 14 |

1
2
3
4
5

1) Black
2) Caucasian
3) Indian
4) Coloured
5) Other (please specify)

_____
_____

4. Do you have Diabetes Mellitus? 15 |

1
2

1) Yes
2) No

5. 1. Do you know the name of the pain relieving injection you received?

1) Diclofenac (Voltaren®) | 1
2) Don't know | 2
3) Other (please specify) | 3

_____
_____

16 | |

5.2. How certain are you of the name of the injection you received?

1) 100% sure | 1
2) 60 – 99% sure | 2
3) < 60% sure | 3

17 | |

6. Who administered the pain relieving injection?

1) General Practitioner | 1
2) Trained Nurse | 2
3) Pharmacist | 3
4) Family member with medical training | 4
5) Family member without medical training | 5
6) Other (please specify) | 6

_____
_____
_____

18-23 | | | | | | |

7. Do you have a scar on the skin from the pain relieving injection?

1) Yes | 1
2) No | 2

24 | |

8. How many pain relieving injections have you ever received?

_____

25-26 | | |

9. Where did you obtain the injection?

1) Hospital Pharmacy
2) General Practitioner
3) Private Pharmacist
4) Other (please specify)

1	
2	
3	
4	

27-30

_____
_____
_____

10.1. If you received the injection from a pharmacist, did you have a prescription?

1) Yes, always
2) Sometimes
3) No

1	
2	
3	

31

10.2. If no to the above question 10.1, how far away do you live from a health care facility that has a medical doctor?

_____km

32-33

11. Have you ever been warned that you may get a skin scar from a diclofenac (Voltaren®) injection?

1) Yes
2) No

1	
2	

34

12. When was the last diclofenac (Voltaren®) injection?

1) Less than one year ago
2) One to five years ago
3) More than five years ago

1	
2	
3	

35

13. When was the injection associated with the scar/scars?

1) Less than one year ago
2) One to five years ago
3) More than five years ago

1	
2	
3	

36

14. After the injection, were any of the following present at the site of the injection?

1) Redness	1
2) Ulceration (skin damage)	2
3) Pain	3
4) Scarring	4
5) Itching	5
6) None of the above	6

37-42

15. Where was the diclofenac (Voltaren®) injection administered?

1) Arm	1
2) Leg (thigh)	2
3) Buttock	3
4) Other (please specify)	4

43-46

_____

16. Did you need any medical treatment for a skin ulcer/abscess after the diclofenac (Voltaren®) injection e.g. antibiotics?

1) Yes	1
2) No	2

47

If yes, please specify what treatment you received

_____
_____
_____

48-49

17. Did you need any surgical treatment for a skin ulcer/abscess?

1) Yes	1
2) No	2

50

Specify:_____
_____
_____
_____
_

51-52

7.5. DATA FORM FOR DOCTOR

1-6

Today's Date: _____

7-9

Patient Number: _____

10-12

Patient Height: _____ (Metres)

13-15

Patient Weight: _____ (Kg)

16-17

BMI: _____

1. Is there a lesion present i.e. scarring/ulceration?

18

1) Yes — 1
2) No — 2

PLEASE ONLY CONTINUE IF YES TO QUESTION 1

2. Identify site of lesion:

19-22

1) Deltoid — 1
2) Gluteus — 2
3) Quadriceps — 3
4) Other (please specify) — 4

_____

3. Hyperalgesia/allodynia present?

23

1) Yes — 1
2) No — 2

4. Decreased sensation present?

24

1) Yes — 1
2) No — 2

5. Size of the scar.

25-28

_____mm (narrowest) x
_____mm (broadest)

6. Any skin colour changes around the lesion.

29

1) Yes, please describe 1
2) No 2

7. Photo taken

30

1) Yes 1
2) No 2

* Please remember to have photographic consent form signed.